

## REMARKS

**Office action summary.** Claims 1-28 and 38-59 are provisionally rejected for obviousness-type double patenting over claims 1-3, 7-16, and 21-61 of copending application No. 10/359,548. Claims 1-7, 27, 29-39, and 49 are rejected as anticipated by U.S. Patent No. 5,945,457 ('457). Claims 1-7, 27, 29-39, 42, and 49 are rejected as anticipated by U.S. Patent No. 5,719,197 ('197). Claims 16-26 are rejected as obvious over either the '457 or the '197.

These rejections are traversed for the reasons indicated below.

**Obviousness-type double patenting.** The provisional obviousness-type double patenting rejection is not well taken because the Examiner is ignoring the limitation, present in all claims, requiring that “the backing member is comprised of a polymer composition that erodes in a moist environment at a slower rate than the hydrogel.”

In an obviousness determination, all claim elements must be taken into account. *See, e.g., Kahn v. General Motors Corp.*, 135 F.3d 1472, 1480-81 (Fed. Cir. 1998) (“In determining obviousness, the invention must be considered as a whole and the claims must be considered in their entirety.”); *Para-Ordnance Mfg. v. SGS Imports Int'l, Inc.*, 73 F.3d 1085, 1087 (Fed. Cir. 1995) (“[W]hen determining obviousness, the claimed invention should be considered as a whole; there is no legally recognizable ‘heart’ of the invention.”). The Examiner’s reasoning that “absent a clear showing of criticality, the determination of a backing member material is within the skill of the ordinary worker” is not in accordance with the law of obviousness. The obviousness inquiry is governed by the *Graham* factors. *Pac-Tec, Inc. v. Amerace Corp.*, 903 F.2d 796, 802 (Fed. Cir. 1990) (citing *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966)). A finding of obviousness requires the Examiner to identify clear and particular suggestion or motivation to modify prior art backing members to make the backing member possess the characteristics recited in the claim, i.e., erosion at a slower rate than the hydrogel in a moist environment. *See, e.g., In re Dembiczak*, 175 F.3d 994, 999 (Fed. Cir. 1999); *B.F. Goodrich Co. v. Aircraft Braking Systems Corp.*, 72 F.3d 1577, 1582 (Fed. Cir. 1996) (“When obviousness is based on a particular prior art reference, there must be a showing of a suggestion or motivation to modify the teachings of that reference.”).

The backing member erosion limitation is not present in the claims of application no. 10/359,548 and is not obvious over those claims. While the Examiner states that the release liner of the '548 application is being interpreted as the backing member called for by the claims of this application (office action p. 3), there is no indication in the '548 claims that the release liner erodes in a moist environment at all, let alone at a slower rate than the hydrogel. For these reasons, the claims of this application are not obvious over the claims of application no. 10/359,548.

**Anticipation rejection of claims 1-7, 27, 29-39, and 49 over '457 patent.** The anticipation rejection of claims 1-7, 27, 29-39, and 49 over the '457 patent is not well taken for a number of reasons. The Examiner identifies the backing member with a polymer backbone as recited in the abstract of the '457 patent (office action at 4). However, there is no indication in the '457 patent that the backbone recited there erodes at all in moist environments, let alone at a slower rate than the hydrogel. Furthermore, because blood is moist, in fact predominantly aqueous, and because the very purpose of the compositions of the '457 is ability to operate in contact with blood, it would seem that any compositions disclosed in the '457 which achieve that objective should not erode in moist environments. Indeed, the '457 describes one of its objectives as producing materials which can be used over "a long term period of weeks, months or years." Col. 2, lines 36-37.

The Examiner reasons that "Since the essential elements of the '457 composition are identical to the instant compositions (that is, a hydrogel composition comprising a hydrophilic polymer capable of bonding to a hydrophilic polymer, a water-swellable polymer, an active agent, and a polymer backbone or 'backing member'), the composition would inherently have the same physicochemical properties as the compositions set forth in the instant application." (Office action at 4.) This is logically fallacious, because not all hydrogel compositions composed of the indicated components erode at all in moist environments. Neither does the backing member necessarily erode less rapidly than the hydrogel itself (as recited in the claims), given that a backing member can be chosen (e.g., of polyethylene) which is water-impervious and does not erode at all. Also, it is wrong to infer that the claimed compositions all have "the same physicochemical properties" as those disclosed in the '457. Among the claimed compositions there are many which have different physicochemical properties, as may be seen from the Examples of the application itself.

What the Examiner seems to be thinking is that if the disclosure of the '457 is viewed at a sufficiently broad level of generality, it discloses a broad class of compositions which purportedly encompasses some of the compositions of the claims, i.e., those compositions of the claims in which the backing member is a "polymer backbone." Under this theory, there would be a modest overlap between the disclosure of the '457, broadly viewed, and what is present claimed. However, mere overlap of a broad generic disclosure with a narrower genus or species later claimed does not establish obviousness. Cf. *In re Baird*, 16 F.3d 380 (Fed. Cir. 1994) (generic disclosure encompassing millions of compositions in prior art reference does not render obvious a particular one of those millions of compositions claimed by a later inventor).

Finally, as indicated above, it is incorrect to view a claim as consisting of "essential" and less essential limitations, as the statement quoted above seems to do. *Para-Ordnance, supra*.

In addition, with respect to the '457, the Examiner writes that "The water-swellable polymer can be methacrylic acid (column 7, line 43), the hydrophilic polymer can be acrylic acid (column 5, line 53) or N,N dimethylaminoalkyl(meth)acrylamide (column 5, line 37)." Claim 1 (on which all other claims depend) recites "a complementary oligomer capable of hydrogen or electrostatic bonding to the hydrophilic polymer," but the Examiner does not identify what the complementary oligomer would be in the '457.

**Anticipation rejection of 1-7, 27, 29-39, 42, and 49 over the '197 patent.** These anticipation rejections over the '197 patent are also not well taken, for the same reasons as the rejection over the '457 is not well taken, i.e., (i) the Examiner has not pointed to any evidence that the compositions of the '197 are erodible or that the backing member erodes more slowly than the hydrogel, (ii) the Examiner's reasoning about "the same physicochemical properties" is logically fallacious, and (iii) the Examiner has not identified a complementary oligomer as required by all claims.

Furthermore, the Examiner appears to be saying that a water-swellable polymer is disclosed on col. 9, line 65 of the '197 patent. That line says "copolymers, acrylic acid, polyacrylates, and polysacch[a]rides." The preceding line ends with "methyl acrylate," so that the word "copolymers" at the beginning of line 65 is part of the phrase "methyl acrylate copolymers." The paragraph containing that line begins by saying "Suitable adhesive carriers include any of the non-toxic polymers"; line 65 is part of a long list of such polymers. Nothing is said there about water-swellability, or water insolubility which is also required by claim 1. The specification of the present application teaches at paragraph 56 that certain acrylate polymers are water-swellable, but that does not imply that all polyacrylates are water-swellable, or water-insoluble as also required by claim 1. Thus, the generic disclosure of polyacrylates in the '197 does not disclose water-swellable, water-insoluble polymers as recited in claim 1.

**Obviousness rejections of dependent claims 16-26.** The Examiner reasons that "Neither '457 nor '197 recite the exact percentage of chemical ingredients as set forth in the instant claims 16-26. However, it would have been within the skill of one of ordinary skill in the art at the time the invention was made to optimize the compositions advanced by either '457 or '197 based on particular use or application." However, the cases which speak of a *prima facie* obviousness of numerical ranges generally do so in the context of varying a single quantity, and require that the prior art reference disclose a value close to the range. *Haynes Int'l, Inc. v. Jessop Steel Co.*, 8 F.3d 1573, 1577 n.3 (Fed. Cir. 1993) ("[W]hen the difference between the claimed invention and the prior art is the range or value of a particular variable, then a *prima facie* rejection is properly established when the difference in range or value is minor.") (emphasis added); *see also, e.g., In re Kumar*, No. 04-1074 (Fed. Cir. Aug. 15, 2005) ("A *prima facie* case of obviousness may be made when the only difference from the prior art is in the

range or value of a **particular** variable.”) (emphasis in bold added); *In re Huang*, 103 F.3d 135, 139 (Fed. Cir. 1997). Here, claims 17-26 address percentages of a number of different variables. One seeking to optimize all of them by experimentation would be found to face a problem of combinatorial explosion. The Examiner does not point to disclosures in the prior art of values for any of these variables. Indeed, for the percentage of complementary oligomer (claims 21 and 26), the Examiner does not point to any disclosure of the variable itself, let alone a value for it.

Claim 16 is a special case because it recites, not particular percentages, but the result to be achieved by them, namely translucency. The Examiner does not point to any prior art disclosure of compositions which meet the remaining limitations of claim 16 and are also translucent. It is therefore not established that a person of skill in the art would have been able to optimize for translucency, as the Examiner contends.

**Conclusion.** For the reasons indicated above, it is requested that the rejections of record be withdrawn and all pending claims allowed. If the Examiner has any questions or concerns, it would be very much appreciated if he would telephone the applicants' counsel at (650) 251-7700.

Respectfully submitted,

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